IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

10621326

Atty. Docket: HOFFMAN=9

In re Application of:	)	Confirmation No.:
Arnold HOFFMAN, et al.	)	Art Unit: Not Yet Assigned
Appln. No.: Not Yet Assigned	)	Examiner:
Filed: July 18, 2003	)	Washington, D.C.
For: REDOX THERAPY FOR TUMORS	)	October 20, 2003

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Mail Stop DD
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

(Check one of the boxes A-D)

[X] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[ ] B. before the mailing date of a first Office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.

[ ] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

(Check one of the boxes "i" and "ii" below:)

[ ] i. Counsel certifies that, upon information and belief, each item of information listed herein was either

[ ] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

[ ] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

(use one and delete other of following)

[ ] ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(p), presently believed to be $180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

[ ] D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant(s) state as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein was either

(Check one of the boxes "a" and "b" below)

[ ] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

[ ] (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(i), presently believed to be $180 is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., Form PTO/SB/08A) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate)

[ ] A. Documents _____ (are) deemed substantially cumulative to documents _____, and,

in accordance with §1.98(c), only a copy of each of the latter documents is enclosed.

[ ] B. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications)

Applicants identify these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 (or PTO/SB/08A) from the files of the prior application(s) or a fresh PTO-1449 (or PTO/SB/08A) listing these documents, and request that they be considered and made of record in accordance with §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

[ ] C. Documents _____ are U.S. patents and/or published applications. As this is a U.S. application filed after June 30, 2003, or an entry into national stage under 35 USC §371 after June 30, 2003, the requirement to file copies of such U.S. patents or published applications has been waived. (Office of Patent Legal Administration - Pre O.G. Notice of July 11, 2003).

3. Documents _____ are not in the English language. In accordance with §1.98(c), Applicants state:

[ ] An English translation of each document _____ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

[ ] A concise explanation of the relevance of documents _____ is found in the attached _____ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[ ] A concise explanation of the relevance of document(s) _____ is set forth as follows:

(insert concise explanation of relevance)

[ ] A concise explanation of the relevance of document(s) _____ can be found on page(s) _ of the specification.

[ ] A concise explanation of document(s) _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. Other information being provided for the examiner's consideration follows:

(insert other information)

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicants reserve the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK
Attorneys for Applicant(s)

By: _____
Roger L. Browdy
Reg. No. 25,618

RLB:zv
624 Ninth Street, N.W., Suite 300
Washington, D.C. 20001-5303
Telephone: (202)628-5197
Facsimile: (202)737-3528
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PTO/SB/08b (08-03)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known	
Application Number	
Filing Date	July 18, 2003
First Named Inventor	Arnold HOFFMAN, et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	HOFFMAN=9

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	AA	R. ARAYA et al; "Hypoxia induces apoptosis in human neuroblastoma SK-N-MC cells by caspase activation accompanying cytochrome *c* release from mitochondria"; *FEBS Lett* (1990); Vol. 439; pages 168-72; Federation of European Biochemical Societies.	
	AB	J. R. BABSON et al; "Inactivation of glutathione reductase by 2-chloroethyl nitrosourea-derived isocyanates"; *Biochem. Biophys. Res. Commun.* (1978); Vol. 83; pages 745-762; Academic Press.	
	AC	D. CEN et al; "Disulfiram induces apoptosis in human melanoma cells: a redox-related process"; *Molec Cancer Ther* (2002); Vol.1; pages 197-204.	
	AD	M.B. COHEN et al; "Characterization of the inhibition of glutathione reductase and the recovery of enzyme activity in exponentially growing murine leukemia (L1210) cells treated with 1,3-bis(2-chloroethyl)-1-nitrosourea." *Biochem Pharm* (1988); Vol.37; pages 3317-3320; Pergamon Press PLC.	
	AE	D.G. CORNWELL et al; "Cytotoxicity of tocopherols and their quinones in drug-sensitive and multidrug-resistant leukemia cells"; *Lipids* (1998); Vol. 33; pages 295-301; AOCS Press.	
	AF	J. DAI et al; "Malignant cells can be sensitized to undergo growth inhibition and apoptosis by arsenic trioxide through modulation of the glutathione redox system"; *Blood* (1999); Vol.93; pages 268-77; The American Society of Hematology.	
	AG	D. L. DUVAL et al; "Regulation of hepatic nitric oxide synthase by reactive oxygen intermediates and glutathione"; *Arch Biochem Biophys* (1995); Vol. 316; pages 699-706; Academic Press Inc.	
	AH	H. ESTERBAUER et al; "Chemistry and biochemistry of 4-hydroxynonenal, malonaldehyde and related aldehydes"; *Free Radic Biol Med* (1991); Vol. 11; pages 81-128; Pergamon Press PLC.	
	AI	T. M. GOTTLIEB et al; "p53 in growth control and neoplasia"; *Biochim Biophys Acta* (1996); Vol.1287; pages 77-102; Elsevier Science B.V.	
	AJ	A. HOFFMAN et al; "Cessation of cell proliferation by adjustment of cell redox potential"; *J Theoret Biol* (2001); Vol. 211; pages 403-7; Academic Press.	
	AK	D. E. HUTTER et al; "Redox state changes in density-dependent regulation of proliferation"; *Exp Cell Res* (1997); Vol.232; pages 435-438; Academic Press.	
	AL	C. D. KANG et al; "Activation of c-jun N-terminal kinase/stress-activated protein kinase and the decreased ratio of Bcl-2 to Bax are associated with the auto-oxidized dopamine-induced apoptosis in PC12 cells"; *Neurosci. Lett.* (1998); Vol. 256; pages 37-40; Elsevier Science.	

Examiner Signature		Date Considered	

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	AM	R. KINSCHERF et al; "Induction of mitochondrial manganese superoxide dismutase in macrophages by oxidized LDL: its relevance in atherosclerosis of humans and heritable hyperlipidemic rabbits"; *FASEB J* (1997); Vol. 11; pages 1317-28.	
	AN	M. KITO et al; "Arsenic Trioxide-Induced Apoptosis and its Enhancement by Buthionine Sulfoximine in Hepatocellular Carcinoma Cel Lines"; *Biochemical and Biophysical Research Communications* (2002); Vol. 291; pages 861-867; Elsevier Science.	
	AO	T. LAHUSEN et al; "Alsterpaullone, a novel cyclin-dependent kinase inhibitor, induces apoptosis by activation of caspase-9 due to perturbation in mitochondrial membrane potential"; *Molec Carcinogen* (2003); Vol. 36; pages 183-194.	
	AP	Y. J. LEE et al; "Glucose deprivation-induced cytotoxicity and alterations in mitogen-activated protein kinase activation are mediated by oxidative stress in multidrug-resistant human breast carcinoma cells"; *J Biol Chem* (1998); Vol. 273; pages 5294-9; The American Society for Biochemistry and Molecular Biology, Inc.	
	AQ	C. J. LI et al; "Potent inhibition of tumor survival in vivo by beta-lapachone plus taxol: combining drugs imposes different artificial checkpoints"; *Proc Natl Acad Sci USA*. (1999); Vol. 96; pages 13369-74.	
	AR	Y. LI et al; "Selective killing of cancer cells by beta-lapachone: direct checkpoint activation as a strategy against cancer"; *Proc Natl Acad Sci USA* (2003); Vol. 100; pages 2674-8.	
	AS	G. LIZARD et al; "Glutathione is implied in the control of 7-ketocholesterol-induced apoptosis, which is associated with radical oxygen species production"; *FASEB J.* (1998); Vol. 12; pages 1651-1663.	
	AT	S. LORD-FONTAINE et al; "Enhancement of cytotoxicity of hydrogen peroxide by hyperthermia in chinese hamster ovary cells: role of antioxidant defenses"; *Arch Biochem Biophys* (1999); Vol. 363; pages 283-95; Academic Press.	
	AU	A. NICOLE et al; "Direct evidence for glutathione as mediator of apoptosis in neuronal cells"; *Biomed Pharmacother* (1998); Vol. 52; pages 349-55; Elsevier, Paris.	
	AV	A. G. PASCHKA et al; "Induction of apoptosis in prostate cancer cell lines by the green tea component, (-)-epigallocatechin-3-gallate"; *Cancer Lett* (1998); Vol. 130; pages 1-7; Elsevier, Paris.	
	AW	C. RAMACHANDRAN et al; "Differential sensitivity of human mammary epithelial and breast carcinoma cell lines to curcumin"; *Breast Cancer Res Treat* (1999); Vol. 54; pages 269-78; Kluwer Academic Publishers.	
	AX	M. M. RIMPLER et al; "Protection against hydrogen peroxide cytotoxicity in rat-1 fibroblasts provided by the oncoprotein Bcl-2: maintenance of calcium homoeostasis is secondary to the effect of Bcl-2 on cellular glutathione"; *Biochem J* (1999); Vol. 340(Pt 1); pages 291-7; Bochemical Society.	

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	AY	L. ROSSI et al; "Quinone toxicity in hepatocytes without oxidative stress"; *Arch Biochem Biophys* (1986); Vol. 251; pages 25-35.	
	AZ	P. K. RUDRA et al; "Acrolein cytotoxicity and glutathione depletion in n-3 fatty acid sensitive- and resistant human tumor cells"; *Anticancer Res* (1999); Vol. 19; pages 461-9.	
	BA	C.K. SEN et al; "Fas mediated apoptosis of human Jurkat T-cells: intracellular events and potentiation by redox-active alpha-lipoic acid"; *Cell Death Differentiation* (1999); Vol. 6; pages 481-91; Stockton Press.	
	BB	R. SMAALAND et al; "Glutathione content in human bone marrow and circadian stage relation to DNA synthesis"; *J Natl Cancer Inst* (1991); Vol. 83; pages 1092-8.	
	BC	A. C. SMITH et al; "Pharmacokinetics of Buthionine Sulfoximine (NSC 326231) and Its Effect on Melphalan-induced Toxicity in Mice"; *Cancer Research* (1989); Vol. 49; pages 5385-5391.	
	BD	S. TAMRAKAR et al; "Role of pRB dephosphorylation in cell cycle regulation" *Frontiers in Bioscience* (2000); Vol. 5; pages D121-137.	
	BE	D. E. THORNTON et al; "Antioxidant and cytotoxic tocopheryl quinones in normal and cancer cells"; *Free Radic Biol Med* (1995); Vol. 18; pages 963-76; Pergamon Press.	
	BF	U. WULLNER et al; "Glutathione depletion and neuronal cell death: the role of reactive oxygen intermediates and mitochondrial function"; *Brain Research* (1999); Vol. 826; pages 53-62; Elsevier Science B.V.	
	BG	A. YAMAUCHI et al; "Control of cell cycle progression in human natural killer cells through redox regulation of expression and phosphorylation of retinoblastoma gene product protein"; *Blood* (1997); Vol. 89; pages 4092-4099.	
	BH	A. ZETTERBERG et al; "Kinetic analysis of regulatory events in G1 leading to proliferation or quiescence of Swiss 3T3 cells"; *Proc Natl Acad Sci USA* (1985); Vol. 82; pages 5365-9.	
	BI	A. ZETTERBERG et al; "Cell cycle progression and cell growth in mammalian cells"; *Frontiers in Molecular Biology: Cell Cycle Control* (1995); pages 2066-2085; Oxford University Press, Oxford, UK.	
	BJ	A. ZETTERBERG et al; "What is the restriction point?"; *Curr Opinion in Cell Biology* (1995); Vol. 7; pages 835-42; Current Biology Ltd .	

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	BK	J. R. ZHOU et al; "Soybean phytochemicals inhibit the growth of transplantable human prostate carcinoma and tumor angiogenesis in mice"; *J Nutrition* (1999); Vol. **129**; pages 1628-35; American Society for Nutritional Sciences.	

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